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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/538,343	GIBSON ET AL.					
Office Action Summary	Examiner	Art Unit					
	Ganapathirama Raghu	1652					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
 Responsive to communication(s) filed on 19 October 2006. This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. 							
Disposition of Claims							
4) Claim(s) 28-49 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 28-49 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 							
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/19/06.	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate					

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Application Status

In response to the Office Action mailed on May 19, 2006, applicants' filed a response and amendment received on Oct. 19, 2006. Said amendment, canceled claims 1-6 and 22-27 and filed a new set of claims 28-49. Thus, claims 28-49 are pending in the instant Office Action and are now under consideration

Objections and rejections not reiterated from previous action are hereby withdrawn.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/19/2006 and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the IDS statement related to this application.

Withdrawn- Claim Rejections 35 USC § 112

Rejection of previous claims 6, 23-24 and 26-27 under 35 U.S.C. 112 second paragraph, is withdrawn in view of the applicants' cancellation of claims 6, 23-24 and 26-27.

Withdrawn- Claim Rejections 35 USC § 102

Previous rejection of claims 1, 2, 5 and 22-23 under 35 U.S.C. 102(e) as being anticipated by Outtrup et al., (USPGPUB: 2005/0215450 A1, publication date of 09/29/2005, which is a DIV of application No.: 10/479446 filed on 12/02/2003 claiming the priority of PCT/DK02/00381 filed on 06/06/2002 and further claiming the priority of provisional

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application No.: 60/302446 filed on 06/29/2001) is withdrawn in view of the applicants' cancellation of 1-27 and amendments to claims.

Claim Objections

Claims 1 and 46 is objected to due to following spelling mistake. Claim 46 in line 3 recites the phrase "... Cellulose..." and Claim 1 in Line 4 and claim 46 in line 4 recites "... glucanase...", the detergent composition comprises two enzymes endoglucanase and cellulase. Correction is required.

Claims 28, 31 and 47 are objected due to the following informality. Claims 28 and 47 recite the phrase "...90% identity to SEQ ID NO: 2" and claim 31 recites the phrase "...70% identity to SEQ ID NO: 4" the metes and bounds of the phrase is not clear and the examiner suggests changing the phrase to "...90% sequence identity to SEQ ID NO: 2 and 70% sequence identity to SEQ ID NO: 4", respectively. Correction is required.

Maintained-Claim Rejections 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-30, 33-45 and 46-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 28-30 and 33-45 are directed to detergent composition comprising (a) anionic tenside, (b) a fungal cellulase and an endoglucanase having a sequence of at least 90% identity to the amino acid sequence of position 1 to 773 of SEQ ID NO: 2 or is a fragment thereof that has endoglucanase activity. Claims 46 and 48-49 are directed to a detergent composition comprising an endoglucanase, wherein the endoglucanase is an anti-redeposition endoglucanase and a cellulose, wherein the detergency benefit from the combination of anti-redeposition endoglucanase and a cellulose is at least 5 units higher than the enzyme detergency benefit of the same detergent without the anti-redeposition endoglucanase and to a process for washing fabric with said detergent composition. Claims 28-30 and 33-45 are rejected under this section 35 U.S.C. 112, because the claims are directed to a genus of polypeptides with no support in the specification for the structural details associated with the function i.e., endoglucanase or cellulase activity. No description of identifying characteristics or functional characterization recognizing all of the sequences i.e., 1) polypeptides having endoglucanase activity from all or any source (as applied to claims 46 and 48-49) and 2) polypeptides having cellulase activity from any or all fungal sources has been provided in the specification (as applied to claims 28-30, 33-45 and 47). No information, beyond the characterization of the polypeptide with SEQ ID NO: 2 or a polypeptide having an amino acid of 1-773 amino acid residues of SEQ ID NO: 2 and having endoglucanase activity or a fungal cellulase having the amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4 has been provided by the applicants, which would indicate that they had possession of the claimed genus of the polypeptides having 1) having endoglucanase activity from any or all sources and 2) polypeptides having cellulase activity from any fungal source. The specification does not contain any disclosure of the sequence and structure of all the polypeptides within the scope of the claimed genus. The disclosed information is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus of polypeptides. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

The applicants' have traversed this rejection with the arguments (page 6 of Applicants' arguments) "cellulose are well known in art and moreover endoglucanase are defined by a precise definition, namely by structure... and applicants submit that that based on the general knowledge available in the art and the information provided in the specification, the disclosure of the application originally filed reasonably conveys to the skilled in the artisan that the inventor had possession of the claimed invention".

The applicants' traversal is answered as follows:

- 1) Claims 28-30, 33-45 and 47 as written have no structural limitations on the recited cellulose, claims 46, 48 and 49 have no structural limitations on either the endoglucanase or the cellulase and specification cannot be imported or read into the claims.
- 2) Claims 28-30, 33-45 and 46-49 as written is directed to a detergent composition comprising a genus of polypeptides with activities of endoglucanase (as applied to claims 46 and 48-49) and cellulase (as applied to claims 28-30, 33-45 and 47) from any source including

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mutants, variants and recombinants of the same and the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of said enzymes. Furthermore, it is well known in the art that structurally related molecules may not possess similar function including desired specificity for substrates and enzyme kinetics and conversely functionally similar molecules may not share similar structural features or significant homology. Therefore, given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 28-49 depending therefrom are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a detergent composition comprising an endoglucanase with anti-redeposition property, comprising a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2, a fungal cellulase having the amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4 and to a process of using the said composition as a detergent, does not reasonably provide enablement for a detergent composition comprising any endoglucanase with anti-redeposition property, having 90% sequence identity to a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 or a fragment thereof and having endoglucanase activity and in addition said detergent composition comprising any polypeptide having at least 70% sequence identity to a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4 or a fragment thereof and having cellulase activity, said composition further broadly comprising any one or more enzymes of claim 37 and to a process of using the said composition as a detergent. The specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with the claim.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 28-49 are so broad as to encompass any detergent composition comprising any endoglucanase with anti-redeposition property, having 90% sequence identity to a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 or a fragment thereof and having endoglucanase activity and in addition said detergent composition comprising any polypeptide having at least 70% sequence identity to a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4 or a fragment thereof and having cellulase activity, said composition further broadly comprising any one or more enzymes of claim 37 and to a process of using the said composition as a detergent. The scope of the claims are not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires knowledge and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant

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of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to the polypeptide sequence of only one endoglucanase i.e., SEQ ID NO: 2 or polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 and the polypeptide sequence of only one cellulase i.e., SEQ ID NO: 4 or a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4. It would require undue experimentation of the skilled artisan to make and use the claimed polypeptides. The specification is limited to teaching the use of the endoglucanase, comprising a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 and the cellulase, comprising a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4, but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claims, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claim, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in

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obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions or deletions.

The specification does not support the broad scope of the claims which encompass any detergent composition comprising any endoglucanase with anti-redeposition property, having 90% sequence identity to a polypeptide having an amino acid sequence of 1-773 amino acid residues of SEQ ID NO: 2 or a fragment thereof and having endoglucanase activity and in addition said detergent composition comprising any polypeptide having at least 70% sequence identity to a polypeptide having an amino acid sequence of 1-229 amino acid residues of SEQ ID NO: 4 or a fragment thereof and having cellulase activity, said composition further broadly comprising any one or more enzymes of claim 37 and to a process of using the said composition as a detergent, because the specification does not establish: (A) regions of the protein/polynucleotide structure which may be modified without affecting the activity of encoded endoglucanase or cellulase; (B) the general tolerance of the polypeptide and the polynucleotide encoding endoglucanase or cellulase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue or the respective codon in the polynucleotide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope

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of the claim broadly including detergents comprising polypeptides with an enormous number of modifications. The scope of the claim must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of endoglucanases with anti-redeposition property and cellulases having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Applicants' have traversed the enablement rejection by stating, specification contains an extensive disclosure of techniques which are well known in the art and indeed routine persons of ordinary skill in the art for identifying other cellulases and endoglucanase for use in the present invention (pages 6-9).

Applicants argue that the rejection under 35 U.S.C. §112, first paragraph is not proper because the specification identifies fungal cellulases and endoglucanases in the present invention while acknowledging some experimentation might be necessary to identify other non-exemplified fungal cellulase and endoglucanase as such experimentation would require carrying out a simple process without special equipment or unusual reaction conditions and within the skill of the ordinary artisan. This is not persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., an endoglucanase having a sequence of 90% identity to the amino acid sequence of position 1 to 773 of SEQ ID NO: 2 or a fragment thereof with endoglucanase activity and a fungal cellulase having a sequence of at least

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70% identity to the amino acid sequence of position 1 to 2999 of SEQ ID NO: 4 or fragment thereof with cellulase activity) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) regions of the protein structure which may be modified without effecting-endoglucanase and cellulase activity; (B) the general tolerance of endoglucanases and cellulases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any - endoglucanase and cellulase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Therefore, given this lack of enablement, the full scope of the claims is not enabled and mere citation of prior art does not overcome this deficiency.

Maintained-Claim Rejections: 35 USC § 103

Addition of new claims has necessitated new rejection with additional reference.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakamada et al., (Biosci. Biotechnol. Biochem., 2000, Vol. 64 (11): 2281-2289) Lund et al., (US Patent No.: 5958082, date of patent 09/28/1999), Schulein et al., (US Patent No.: 6001639, date of patent 12/14/1999), Clarkson et al., (US Patent No.: 5290474, date of patent 03/01/1994) in view of Herbots et al., (US Patent No.: 6030933, date of patent 02/29/2000).

Hakamada et al., (*supra*) disclose the purification, kinetic profiles, thermostability and biophysical characterization of an alkaline endoglucanase (Abstract section, page 2281) having 98.3% sequence homology to SEQ ID NO: 2 of the instant application (see sequence alignment provided). The said enzyme is suitable for use as an effective detergent additive (Introduction section, page 2281) and has pH optima of about 9.0 in 0.1 M glycine-NaOH buffer (Results and Discussion section, third paragraph, page 2286).

Lund et al., and Schulein et al., (*supra*) disclose detergent composition with anionic tensides (page 35, paragraph 3 of Schulein et al.,) and comprising a polypeptide having a cellulase activity from *Thielavia terrestris* NRRL 8126 (Lund et al., claims 1 and 7; same source as the instant application) with 100% homology to SEQ ID NO: 4 of the instant application (see copy of the sequence alignments provided).

Clarkson et al., (supra) disclose the detergent compositions consisting of endoglucanase and cellulase plus other enzymes like exo-cellobiohydrolase, β -glucosidase and a method for washing fabrics with said detergent composition, wherein the weight ratio of said endoglucanase protein component to the total enzyme protein ranges from 20%-50% i.e., 1:5-1:2 (Column 4, Detailed description of the invention) and claim 1, wherein endoglucanase protein component to the total enzyme protein is 40% i. e., 1: 2.5 (column 24).

One of ordinary skill in the art would be motivated to make a detergent composition comprising endoglucanase with anti-redeposition property (as taught by Hakamada et al.,) and cellulase (as taught by Lund et al., Schulein et al., and Clarkson et al.,) or a detergent composition comprising additional enzymes or mixtures thereof (as taught by Herbots et al.,), as the above cited references teach the properties of the enzymes and their use as fabric and textile detergents and other related applications including the appropriate weight ratio of the

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endoglucanase component to the total enzyme protein in the detergent composition and processes and applications of said detergent compositions. One of ordinary skill in the art would have a reasonable expectation of success, because of the clear establishment of the properties and the role of the enzymes, endoglucanase and cellulase or detergent composition comprising mixtures of other enzymes with known bio-physical and bio-chemical properties in the combined teachings for the production and use of a detergent composition.

Therefore, the above references render claims 28-49 *prima facie* obvious to one of ordinary skill in the art.

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

- 1) New claims 1, 28, 31 and 46-47 are objected due to informalities.
- 2) New claims 28-30, 33-45 and 46-49 are rejected under 35 U.S.C. first paragraph for written description.
- 3) New claims 28-49 are rejected under 35 U.S.C. first paragraph for scope of enablement.
- 4) New claims 28-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakamada et al., (Biosci. Biotechnol. Biochem., 2000, Vol. 64 (11): 2281-2289) Lund et al., (US Patent No.: 5958082, date of patent 09/28/1999), Schulein et al., (US Patent No.: 6001639, date of patent 12/14/1999), Clarkson et al., (US Patent No.: 5290474, date of patent 03/01/1994) in view of Herbots et al., (US Patent No.: 6030933, date of patent 02/29/2000).

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Conclusion

None of the claims 28-49 are allowable. Claims 28-49 are rejected for the reasons identified in the Rejections and Summary sections of this Office Action. Applicants must respond to the objections/rejections in each of the sections in this Office Action to be fully responsive for prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 4.30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D. Patent Examiner Art Unit 1652

Dec. 02, 2006.

REDECCA E. PHOUTY
PRIMARY EXAMINER
GROUP